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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,732	07/31/2001	Piero Anversa	674554-2002	6924

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,732	1636	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D	1633	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-153 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-153 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-153 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

I. Claims 1-25, 88-98, 101-123, 141-142 and 147-151, drawn to a method for repairing and/or generating and/or regenerating myocardium and/or myocardial cells comprising the administration of somatic stem cells; a method of implanting or depositing cells or causing the implantation or depositing of somatic stem cells in cardiac or blood vessel tissue comprising administration of somatic stem cells; a pharmaceutical composition comprising a therapeutically effective amount of somatic stem cells; a kit and a method for making the same pharmaceutical composition, classified in class 424, subclass 93.1.

II. Claims 26-52 and 124-140, drawn to a method of repairing and/or regenerating recently damaged myocardium and/or myocardial cells comprising the administration of a cytokine; a method of implanting or depositing cells or causing the implantation or depositing of somatic stem cells in cardiac or blood vessel tissue comprising administration of a cytokine, classified in class 424, subclass 85.1.

III. Claims 53-87, 99-100, 143-144 and 147-152, drawn to a method of repairing and/or generating and/or regenerating recently damaged myocardium and/or myocardial cells comprising the administration of somatic stem cells and a cytokine, a pharmaceutical composition comprising a therapeutically effective amount of somatic cell and a selected cytokine; a kit and a method for making the same pharmaceutical composition classified in class 424, subclasses 93.1, 85.1.

IV. Claims 145-146, drawn to a pharmaceutical composition for use in the treatment, therapy or prevention of cardiovascular disease or related complaint and a pharmaceutical composition for use in repairing and/or generating and/or regenerating recently damaged myocardium and/or myocardial cells, can not be classified because the chemical structure of the composition is not recited.

V. Claim 153, drawn to a method of treating damaged myocardium and/or myocardial cells comprising the recited steps, classified in class 435, subclass 1.1.

The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because the methods in Groups I-III and V appear to constitute patentably distinct inventions for the following reasons: These methods are directed to methods that are distinct both physically and functionally, and are not required one for

the other. For examples, the methods of Group I require the **administration of somatic stem cells** for repairing, generating, regenerating myocardium or myocardial cells of for implanting or depositing of somatic stem cells in cardiac or blood vessel tissue; the methods of Group II require the **administration of a cytokine** for repairing, regenerating recently damaged myocardium or myocardial cells or for implanting, depositing of somatic stem cells in cardiac or blood vessel tissue; the methods of Group III require the administration of **both somatic stem cells and a cytokine** for repairing, regenerating recently damaged myocardium or myocardial cells; the method of Group V requires **the implantation of cardiac structures** assembled in vitro from the differentiated and proliferative cultured somatic stem cells. These methods involve different method steps, different starting materials and different technical considerations for attaining the desired end-results, and they can be practiced independently from each other.

Additionally, the products of Groups I-III are unrelated to the product of Group IV because the product of Group IV is not constituted of somatic stem cells, a cytokine or a combination of somatic stem cells and a cytokine. The composition of the product of Group IV is not even recited. The products of Groups I-III are distinct in their compositions. For examples, the product of Group I is composed of somatic stem cells; whereas the product of Group II is made up of a cytokine and the product of Group III is made up of somatic stem cells and a cytokine, and that these products can be used independently.

Claims 147-151 contain multiple patentably distinct compositions which lack unity of invention, namely: (a) a kit comprising a pharmaceutical composition of claim 88, a kit and a method for making the same, and (b) a kit comprising a pharmaceutical composition of claim 99, a kit and a method for making the same, which lack the unity of invention for the reasons already discussed above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

A. Should Applicants elect Group I, claims 1, 11, 13, 18-25 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named differentiated cell type as recited in the Markush Group of claim 19.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

B. Should Applicants elect Group II, claims 26-52 and 124-125 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named cytokine as recited in the Markush Group of claim 27 or claim 125.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 26-28, 33 and 43-52 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named differentiated cell type as recited in the Markush Group of claim 46.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

C. Should Applicants elect Group III, claims 53, 71-87, 99-100 and 143 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named cytokine as recited in the Markush Group of claim 71 or claim 143.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 53, 71-72, 74, 77 and 79-87 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named differentiated cell type as recited in the Markush Group of claim 81.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER